



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

2812 5 NOV 29 4 54 PM
Food and Drug Administration
Rockville, MD 20857

November 28, 2005

James O. Maloy
Fulcrum Inc.
23 Carol Street
Clifton, NJ 07014

Dear Mr. Maloy:

Thank you again for writing to the Food and Drug Administration (FDA). This is in response to your letter dated October 7, 2005, to Dr. Steven K. Galson, commenting on the Agency's response to your November 14, 2003, citizen petition (Docket No. 2003P-0531/CP1). Your letter was forwarded to my office in the Center for Drug Evaluation and Research (CDER), Division of Drug Information (DDI), for a response.

I have taken the liberty of forwarding your letter (with enclosure) to Dockets Management so that it can be recorded and considered as an official comment to our response of your citizen petition.

Again thank you for writing. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Donald Dobbs
Division of Drug Information (HFD-240)
Office of Training and Communications
Center for Drug Evaluation and Research
Food and Drug Administration

2003P-0531

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